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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,956	10/01/2003	Suzanne Zebedee	323-100US D	9260

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/677,956	ZEBEDEE ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-123* is/are pending in the application.

4a) Of the above claim(s) *115 and 119-123* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112-114* is/are rejected.

7)☒ Claim(s) *116-118* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3 lists*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 112-123 are pending in the application.

Election/Restrictions

2. Applicant's election of Group I, and species (B)- drawn to binding agents that are anti-human IgG antibodies, (5)- drawn to fluorescent labels, and (ii) drawn to antigens having the capsid sequence of residues 21-40, in the reply filed on April 3, 2006 (including the amendment of May 5, 2006- correcting certain informalities) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 115 and 119-123 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species or inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 3, 2006.

It is noted that the Applicant asserts on page 43 of the April 3, 2006 response that claims 112-118 are each inclusive of species (5). However, this species requires the use of a fluorescent label, as opposed to the labels of non-elected species (1)-(4). Claim 115 presents non-elected species (1)-(4) as the only options for labels, and thus does not read on the elected species.

4. Claims 112-114, and 116-118 are under consideration.

Priority

5. The reference in the specification to the priority applications 563,732; 272,271; 616,369; and 573,643 is objected as not properly identifying the applications by their complete reference numbers as follows: 08/563,732; 08/272,271; 07/616,369; and 07/573,643.

Further, the application does not provide the relationship of the parent application 08/931,855 with application 08/272,271. In particular, it is noted that, according to MPEP 202.11 III.A., the reference to each parent application must identify the relationships among the various independently. I.e., the relationship of one application to another must identify the relationships of one application to one parent application at a time (A is a continuation of B), and not cumulatively (A is a continuation of B and C).

Appropriate correction is required.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on November 24, 2003; and February 13, and March 9, 2006, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements been considered by the examiner.

Specification

7. The disclosure is objected to because of the following informalities: the Applicant has amended the Brief Summary of the Drawings such that it no longer refers to Figures 9 or 10. It is suggested that the specification be amended to indicate that Figure 9 discloses the DNA (SEQ ID NO: 30) and protein (SEQ ID NO: 73) sequences of the capsid protein of the Hutch strain of NANBV; and that similar amendments be made with reference to Figure 10.

It is also noted that there does not appear to be a Brief Summary of the Drawing with respect to Figures 11-19.

Appropriate correction is required.

Claim Objections

8. Claims 116-118 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 115. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

9. Claim 112 is objected to because of the following informalities: the claim delineates the separate steps of the claim using numbers. The use of letters is preferable so as to avoid confusion with the numbering of the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 112-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are drawn to methods for detecting seroconversion associated with HCV infection of an individual "at early times after infection." The phrase " at early times after infection " in claim 113 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are therefore rejected as indefinite.

It is suggested that the claims be amended to indicate that the method detects seroconversion at an earlier time that is detected when using a C-100 based immunoassay, as identified on page 104 of the application, or through deletion of the indicated language.

12. Claims 113-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 113 purports to further limit claim 112 to embodiments wherein step (c) additionally comprises substeps (iii)-(vi). Claim 114 depends from claim 113. The claims are indefinite because there is no antecedent basis for a step (c) in claim 112. While claim 113 appears to be further limiting detection step 3. of claim 112, in view of the disparity between the reference to the detection steps between claims 112 and 113, it is not clear that this is the case. Further, it is noted that there are no substeps (i)-(iii) in either claim 112 or claim 113. Thus, it is not clear what the implicitly references steps (i)-(iii) comprise of.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 112-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Wang et al. (U.S. 5,106,726) in view of the teachings of Houghton et al. (EP 0 318 218- of record in the March 2006 IDS). These claims are drawn to method for the early detection of HCV (NANBV) seroconversion through the use of an HCV core (capsid) antigen for the detection of anti-HCV antibodies.

Wang teaches methods for the detection of anti-HCV antibodies in samples through the use of HCV antigens including the C-100 antigen (a non-structural protein antigen) and the core antigen. See e.g., Abstract. Moreover, the reference teaches that methods in which the core antigen is used result in a more sensitive assay. See e.g., columns 43-45. In particular, the reference teaches that not only are assay that include the use of the core antigen more sensitive that those with the C-100 antigen, but that such assays were able to identify HCV positive specimens four to eight weeks earlier that C-100 based assays (Format A in the patent). Column 44, lines 27-38. Thus, the reference teaches a method for the early detection of HCV antibodies through the use of an HCV core antigen. Moreover, it is noted that the core antigen disclosed by the peptide includes the sequence of residues 21-40 of SEQ ID NO: 73. See e.g., Claim 1, peptide vii. However, while the reference teaches the detection of anti-HCV antibodies in fluid samples (abstract) the reference does not teach the claimed methods wherein the sample and the antigen are combined to form an aqueous immunoreaction admixture, or embodiments wherein the immunoreaction product (antigen bound by human anti-HCV antibodies in the sample) are detected using an anti-human IgG antibody.

However, the use of such methods was known in the art at the time of invention. For example, Houghton teaches that different protocols may be used for the detection of HCV

antibodies or antigens. Page 20. The reference indicates that the protocols may involve either the use of a solid support, or be in an immunoprecipitation format (where the sample and the target antigen/antibody are both soluble- i.e. an aqueous immunoreaction admixture). Id., at lines 31-32. In addition, the reference also teaches that bound anti-HCV antibodies may be detected through the use of anti-human IgG antibodies. See e.g., page 44, lines 57-58. As the reference indicates that the immunoprecipitation and use of anti-human IgG antibodies were recognized in the art as useful alternatives to the immunodetection assay and components in the method of Wang, it would have been obvious to those of ordinary skill in the art to have used the format suggested by Houghton in the place of that of Wang. Those of ordinary skill in the art would have had a reasonable expectation of success in the use of the alternative format because it was an accepted alternative to the solid substrate format used by Wang, and in view of the teachings of Wang indicating that it was the use of the core antigen, not the format of the assay, that resulted in the improved sensitivity of the assay. The combined teachings of these references therefore render the claimed methods obvious.

Conclusion

15. No claims are allowed.

16. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Okamoto et al., Japan J Exp Med, 60: 223-33 (of record in the November 2003 IDS). Like the Wang reference applied above, this reference teaches that the use of the HCV core antigen resulted in the earlier identification of HCV antibodies. Page 231, left column. However, the reference does not appear to be prior art based on the letter filed in

parent application 07/616,369 on February 16, 1993, indicating that the reference was not publicly available until at least the end of October 1990, after the priority date of the present application with respect to the presently claimed method.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Z. Lucas
Patent Examiner